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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/1106

EXAMINER

SRIVASTAVA, K

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

11/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/555,906

Applicant(s)

Katy Drieu

Examiner  
Dr. Kailash C. Srivastava

Group Art Unit  
1651



☒ Responsive to communication(s) filed on Jun 2, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☒ Claim(s) 1-13 is/are objected to.

☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

☐ Claims \_\_\_\_\_

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part of Paper No. 5

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## DETAILED ACTION

1. Claims 2-8 and 11-13 are presented for examination.
2. Applicant's preliminary amendment, filed on June 2, 2000 (Paper Number 3) has been entered. Claims 1 and 9 have been cancelled.

### *Claim Rejections - 35 U.S.C. § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

4. Claims 2-3, 6-8, and 11-13 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
    - o The recitation, "EGb761" in claim 2 is indefinite because this term does not clearly define the composition of *Ginkgo biloba* extract. The applicant is advised to define the term in this claim.
    - o The term, "CP 401" in claim 3 is indefinite because the term does not clearly define the composition of *Ginkgo biloba* extract. The applicant is advised to define the term in claims.
    - o The term "O-Gs" is indefinite in claims 6-8 because it is not clear what the recitation means.
    - o The recitation, "derivative" in claim 6 is unclear as well as confusing, and therefore indefinite because the term does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter.
    - o In Claim 6, lines 20-22 of page 13 do not follow logically from the remainder of the claims.
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- o Also it is not clear whether the subject matter recited as "such as" is necessarily in the claim or merely exemplary.
- o The recitation "toxicomania" in Claim 12 is indefinite. The term "toxicomania" is not defined by the claim, the specification does not provide a standard for ascertaining the meaning of this term, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
- o The term "pharmaceutical salt" in claim 13 is an undefined and unknown term that renders the claim indefinite. The term "pharmaceutical salt" is not defined by the claim, the specification does not provide a clear cut meaning of this term, and one skilled in the art would not be reasonably apprised of the scope of the invention because the meaning of this term is not clear. Note that the term "pharmaceutically acceptable salt" is acceptable.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

6. Claims 2-5 and 11-13 are rejected under 35 U.S.C. § 103(a) as obvious over Hsia et al. (U.S. Patent 5,976,548) and Kleijnen et al (Lancet, 340:1136-1139, 1992) in view of Remington's Pharmaceutical Sciences.

Claims 2-3 recite the types of ginkgo extracts. Claims 4 and 5 recite that *Ginkgo biloba* extract contains 5-50% ginkgolides. Claim 11 recites "a method to ease withdrawal symptoms of substance abuse" in a human being, such ease being effected by administering a ginkgo extract preparation.

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Hsia et al. teaches that a nutritional supplement containing ginkgo extract enhances memory, improves mental activity (column 2, lines 55-59), mental awareness and intellectual performance (Column 3, lines 1-3) and helps overcome absent-mindedness, confusion and headaches (column 4, lines 34-39).

Kleijnen et al., discloses that pharmaceutical extracts from ginkgo leaves have been used to treat cerebral insufficiency (Page 1136, Column 1, lines 42-45), that includes absent mindedness, anxiety, depression, dizziness and headache (Page 1136, Column 2, lines 1-4).

Remington's Pharmaceutical Sciences teaches that withdrawal symptoms from alcohol abuse are manifested as headache, nausea, insomnia, confusion, disorientation and hallucination (pg. 1291, Column 1, Paragraph 1). Cigarette smoking, teaches the same reference, renders cerebrovascular insufficiency, interference with central nervous system processes and psychological stress (page 1292, column 1-2). Withdrawal from amphetamine abuse results in psychoses.

Both, Hsia et al., and Kleijnen et al., do not teach the use of ginkgo extract to ease the withdrawal symptoms of substance abuse, or drug addiction, while Remington's Pharmaceutical Sciences merely describes the symptoms of drug addiction, substance abuse and substance abuse withdrawal.

However, learning from the disclosure in Remington's Pharmaceutical Sciences about the repercussions of substance abuse, and symptoms of substance abuse withdrawal, and in view of the teachings of Hsia et al., and Kleijnen et al., that ginkgo extract in a dietary composition helps overcome the symptoms that are similar to those manifested by an individual who is recuperating from substance abuse, the artisan of ordinary skill would have been motivated to give ginkgo extract to ease the withdrawal symptoms of substance abuse to a human being.

The *Ginkgo biloba* extract that Kleijnen et al., disclose also contains ginkgolides (Page 1138, Column 1, lines 38-40). Kleijnen et al., however, do not disclose the same amounts of ginkgolides as are

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present in the composition recited in Claims 4 and 5. However, in view of the clear disclosure of desirability of composition containing ginkgolides, the determination of suitable amount of those ingredients would have been a routine matter of optimization on the part of the artisan of ordinary skill, and therefore obvious under 35 U.S.C. § 103(a).

Thus an artisan of ordinary skill would have been motivated to prepare a ginkgo extract that contains 5-50% ginkgolides and use that ginkgo extract to overcome the withdrawal symptoms of an individual rehabilitating from drug addiction.

7. Claims 6-8 and 10-13 are rejected under 35 U.S.C. § 103(a) as obvious over Hsia et al., Kleijnen et al., and Remington's Pharmaceutical Sciences in further view of Park et al. (U.S. Patent 5,541,183).

Claims 6-8 additionally recites general formula of a compound wherein 4 loci may be replaced with anyone of H, OH, linear or branched alkoxy- or O-Gs radicals. "Gs-OH representing mono- or disaccharide or one of their derivatives or analogues". These compounds are used to prepare a medicament to ease withdrawal of individuals dependent on drug addiction.

Park et al. describes methods to synthesize a number of compounds (column 1, lines 10-20, column 4, lines 20-39 and 51-63) with a structure of that recited in claims 6-8. These compounds are also ginkgolide derivatives that have pharmaceutical uses (abstract).

Thus, an artisan of ordinary skill would have been motivated to utilize the teachings from Park et al., to synthesize the derivatives of ginkgolides recited in the instant claims and prepare medicaments containing those derivatives to ease withdrawal symptoms of individuals dependent on drug addiction as suggested by Hsia et al.

Claim 10 recites that ginkgolides A and B are the components of *Ginkgo biloba* extract used to ease withdrawal symptoms.

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Kleijnen et al., and Hsia et al., disclose that their ginkgo extract used for the treatment of depression, dizziness, and headache (See, e.g. Kleijnen et al., at Page 1138, Column 1, lines 38-40) contains ginkgolides A and B and the concentrations of these ginkgolides available to the subject in their ginkgo extract is 50-70% (See Kleijnen et al., at Page 1138, Column 1, lines 38-45).

Park et al., disclose pharmaceutical composition containing ginkgolides A and B (Column 2, lines 24-38), teach synthesis of ginkgolide B derivatives (Column 7, line 12 to Column 10, line 32) and provide pharmaceutical compositions containing ginkgolide B derivatives.

Both, Park et al., and Kleijnen et al., does not teach the use of ginkgo extract containing ginkgolides A and B, or derivatives of ginkgolide B to ease the withdrawal symptoms of substance abuse, or drug addiction.

However, learning from the disclosures of Park et al., and Kleijnen et al., that ginkgo extract containing ginkgolides A and B helps overcome the symptoms that are similar to those manifested by an individual who is recuperating from substance abuse as discussed in Remington's Pharmaceutical Sciences, the artisan of ordinary skill would have been motivated to make ginkgo extract containing 5-10% ginkgolides A and B, or derivatives of ginkgolide B to ease the withdrawal symptoms of substance abuse to a human being.

As discussed above, Hsia et al., and Kleijnen et al., in view of Remington's Pharmaceutical Sciences render Claim 11 obvious.

Remington's Pharmaceutical Sciences also teaches that alcohol, cigarette smoking, amphetamines and other drugs may cause drug addiction. It further discloses the symptoms of addiction to the referred drugs and elucidates that withdrawal symptoms in an individual who withdraws from addiction of alcohol, or alcohol abuse are manifested as headache, nausea, insomnia, confusion, disorientation and hallucination

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(Page 1291, Column 1, Paragraph 1). Cigarette smoking, teaches the same reference, renders cerebrovascular insufficiency, interference with central nervous system processes and psychological stress (page 1292, column 1-2). Withdrawal from amphetamine abuse results in psychoses. This reference also discloses similar information for other drugs (see page 1297 for a list of other drugs).

Based on the disclosure in Remington's Pharmaceutical Sciences, an artisan of ordinary skill would have been apprised of the drugs that can cause drug addiction and of the withdrawal symptoms in an individual withdrawing from the addiction to such drugs. Therefore, an artisan of ordinary skill would have been motivated to select individuals withdrawing from dependency or addiction from alcohol, amphetamine or cigarette smoking (tobacco).

Claim 13 recites selection of ginkgolides, pharmaceutical salt of a ginkgolide or glycosylated, alkoxyated- or acetylated ginkgolide.

Park et al., disclose synthesis of ginkgolide B derivatives that are acetylated and alkoxyated (Column 6, lines 4-6) and provide pharmaceutical compositions containing ginkgolide B derivatives.

Park et al. does not teach synthesis of glycosylated ginkgolides.

Kleijnen et al. disclose that their ginkgo extract for the treatment of depression, dizziness, and headache (Page 1136, Column 2, Lines 1-4) contains ginkgolides A and B (Page 1138, Column 1, Lines 38-40).

Both, Park et al., and Kleijnen et al., does not teach the use of ginkgo extract containing ginkgolides A and B, or derivatives of ginkgolide B to ease the withdrawal symptoms of substance abuse, or drug addiction.

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However, learning from the disclosures of Park et al., about synthesis of acetylated and alkoxyated ginkgolides, an artisan of ordinary skill would have been motivated to prepare glycosylated ginkgolides through substitution of mono-, di-, or polysaccharides to obtain the glycosylated ginkgolides claimed in the instant invention. Having synthesized glycosylated ginkgolides, the same artisan would have been motivated to incorporate the ginkgolides either as such or as a salt in to the pharmaceutical composition of Kleijnen et al. to prepare pharmaceutical compositions to ease withdrawal symptoms.

Thus, the cited references show that at the time of the invention, it was well known in the art that ginkgo extract containing ginkgolides A and B or derivatives of ginkgolide B are useful in overcoming symptoms that are also manifested by an individual rehabilitating from drug addiction. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by Hsia et al., Kleijnen et al., and Park et al., that the ginkgo extract containing ginkgolides A and B, or derivatives of ginkgolide B referred in the cited references are used in pharmaceutical compositions to treat symptoms that are manifested by an individual undergoing drug addiction rehabilitation, an artisan of ordinary skill would have had a reasonable expectation that a combination of all these substances would also be useful to ease withdrawal symptoms in an individual undergoing drug addiction rehabilitation. Therefore, the artisan would have been motivated to combine all these components into a pharmaceutical preparation for the intended purpose. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

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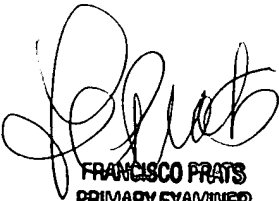
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:45 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Patent Examiner  
Art Unit **1651**  
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FRANCISCO FRATS  
PRIMARY EXAMINER

November 3, 2000

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